

J Canc Educ (2010) 25:142–145
DOI 10.1007/s13187-009-0032-y

Adapting a Program to Inform African American and Hispanic American Women About Cancer Clinical Trials

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Published online: 10 February 2010

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Abstract The dearth of evidence-based clinical trial education programs may contribute to the underrepresentation of African American and Hispanic American women in cancer research studies. This study used focus group-derived data from 80 women distributed among eight Spanish- and English-language focus groups. These data guided the researchers' adaptation and refinement of the National Cancer Institute's various clinical trials education programs into a program that was specifically focused on meeting the information needs of minority women and addressing the barriers to study participation that they perceived. A "sisterhood" theme was adopted and woven throughout the presentation.

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Keywords MeSH · African American · Breast cancer ·
Clinical trials · Disparities · Focus groups ·
Hispanic American · Latinas · Recruitment

Introduction

African American and Hispanic American (AA/HA) women have high breast cancer mortality rates, 34.4% and 16.3%, respectively, [1] and are underrepresented in clinical trials designed to identify effective cancer control strategies [2–7]. This underrepresentation limits the degree to which research findings can be generalized to underrepresented groups with confidence and thereby likely contributes to widening the health disparities gap for AA/HA women. While some minority women are reluctant to join research studies, others lack the information necessary to explore these options [8]. Some are never offered the information, while others lack the scientific framework needed to make an informed decision [5].

Clinical trial educational programs designed specifically for AA/HA women could help address these problems. The National Cancer Institute (NCI) created the Clinical Trials Education Series, but according to the then director of the program, the programs were found to be disappointing when used with members of communities that are traditionally underrepresented in research studies (personal communication with Margo Michaels). This research team hypothesized that NCI's program could be adapted to give it greater appeal to AA/HA women and refined so it would address minority women's specific concerns. Seeking to avoid the cost and inefficiencies of creating and delivering multiple culturally specific programs for each of the nation's dozens of minority groups that are also underrepresented in research studies, the

researchers hypothesized that weaving a “sisterhood” theme throughout the program would enable a single program to be effective for women from diverse communities. Further, if the program was created as a slide show rather than a video, it would then be relatively inexpensive to translate a single program into multiple languages and swap out photos, as had originally been intended for the NCI’s Clinical Trials Education Series.

Methodology

Qualitative methods of inquiry enhance understanding of the insider perspective of the participants [9] and facilitate research focusing on cultural issues and diverse ethnic populations because these methods involve the in-depth exploration of a phenomenon, which is grounded in the world view, vocabulary, and experiences of those being studied [10]. Thus, the use of focus group methodology was anticipated to allow the research team to gain insight into participants’ beliefs and attitudes about clinical trials and a medium for their voices to be heard.

This study used focus groups to guide the adaption of NCI’s “Cancer Clinical Trials: The Basics” and *Conversemos un rato: Información para combatir el cáncer en su comunidad* PowerPoint educational programs into a form that would be culturally aligned with the beliefs and attitudes of AA/HA toward clinical trials. “The Basics” program is a 28-slide presentation covering topics such as: what are clinical trials, phases of clinical trials, randomization, types of trials, protocols, and barriers to participation. The *Conversemos un rato* program contains 58 slides, is only available in Spanish, and covers topics more in-depth than “The Basics” program, such as: what are clinical trials, who takes part in clinical trials, types of trials, protecting patients’ safety, risks and benefits of trials, where to find trials, and issues of concern to Latino audiences. Both programs are available for public use on the NCI’s website (<http://www.cancer.gov/clinicaltrials/resources/clinical-trials-education-series>). Core content from “The Basics” presentation, in addition to two slides with testimonials and photographs from the *Conversemos un rato* program and additional non-copyrighted photographs and artwork from free internet sources were used to create a program by the research team that would have universal appeal to AA/HA women. The modified program shown to focus group participants consisted of 36 slides and required approximately 30 min to view.

To start this process, the authors gave the new presentation a sisterhood title and title slide and included additional pictures of women from different ethnic groups who were of diverse ages and careers throughout the presentation. These changes were anticipated to give this presentation a more universal appeal. Other adaptations perceived to be appropriate were to

more clearly define terms and more clearly connect concepts to the benefits minority women might derive from participating in research studies. Two testimonials about women’s experiences in learning about and enrolling into clinical trials were also incorporated into the presentation based on the NCI’s positive responses to these elements of its programs.

This presentation was then shown to four focus groups of ten women each. One group was composed of African American women, one of Hispanic American women who preferred to communicate using English, one of Hispanic American women who preferred to communicate using Spanish, and one that included both African American and Hispanic American English-speaking women together. Focus groups took place at convenient community-based locations, such as a neighborhood community center, church, community clinic, and participants’ homes.

All focus group participants were consented in English or Spanish according to the UCSD IRB-approved protocol and given a copy of the Human Subject’s Bill of Rights. Being mindful of lack of trust in research as a major barrier to participating in clinical trials [5, 11], to facilitate an open, trusting environment in which participants would be comfortable to voice their opinions, approximately 20–30 min was devoted to introductions, during which light refreshments and snacks were served. Additionally, each focus group moderator was culturally aligned with the focus group participants, meaning they reported themselves to be of the same ethnic group [12].

The moderator read a script that corresponded to the PowerPoint slides. Participants were told that the presenter would pause between slides to allow the participants to write down their impressions and suggestions for improving the slide. Specifically, they were told that while they could ask questions between the slides, the presenter preferred that they record their questions to see if the questions were adequately addressed in subsequent slides. The rationale behind these instructions was that the educational program was created to be a self-administered program, with the opportunity to meet with a nurse or health educator afterwards to answer any questions not adequately addressed in the presentation.

Including the time allowed for recording notes between the slides, the 36-slide presentation required approximately 30 min. Additionally, 45 min were allotted for discussion. Thus, from consent to completion, about 2 h were required. At the end of the focus group, participants were given \$35 in appreciation for their time.

Results

After each focus group, the researchers reviewed their field notes from the focus group, highlighted comments that

were offered, and then clustered the comments into themes [9, 13]. Themes for each of the four groups were collated, and subsequent changes were made to the PowerPoint presentation in response to the focus group feedback. From the first series of focus groups, five main themes emerged on how to enhance the program for AA/HA women.

The first theme focused on changes needed to the presentation's overall format. For example, participants felt the slides needed more pictures and fewer words. They underscored the importance of creating aesthetically appealing slides that would help retain the viewers' attention. Participants also noted inconsistencies in the format among the slides that they found distracting. These factors impact the effectiveness of educational programs, but can be easily overlooked in program design.

For the second theme, the participants told the researchers that the purpose of the presentation needed to be made clearer. They wanted, for example, a clearer rationale for why minority women should be concerned about clinical trials and why scientists were concerned with recruiting minority women to clinical trials. They wanted more attention given to the varieties of clinical trials, including information about clinical trials for women without cancer. They also wanted less information per slide and less detailed attention to nuances, feeling that this could be offered after the women were more engaged in the informed consenting process.

For the third theme, participants reported that the overall concept of the sisterhood theme was not adequately emphasized and that there should be a reference to it on every slide to tie in the theme throughout the entire program. Women wanted to feel that the presentation was directed specifically at them. They suggested adding testimonials from women who had gone through clinical trials to help the women relate to the overall clinical trials participation message. They wanted to be able to see women's faces and hear their voices and preferred photos over drawings of women. The participants also recommended that the pictures should show women of diverse cultures working together, instead of pictures depicting individual women from diverse cultures. Further, they suggested that the voice-over should use the first-person terms of "our," "we," and "us," instead of third-person phrasing of the information. Participants suggested that using such personal pronouns could elevate camaraderie and motivation for women to battle cancer together through clinical trials.

The fourth theme was the need for a better definition of the term clinical trials and to place it earlier in the presentation, because many women would not be familiar with this concept. Participants emphasized the importance of using simplified vocabulary and pictures and drawings to explain complex ideas, such as informed consent or randomization.

For the fifth theme, participants felt there was a need to more effectively explain the benefits and barriers of participating in clinical trials. They agreed that the fear about clinical trials was a significant impediment to clinical trials participation and needed to be addressed, along with topics such as insurance coverage for clinical trials, privacy issues, and safety assurances during the clinical trial process. Participants felt that these issues were among the greatest obstacles that women would face in the initial decision making related to clinical trial participation and that these issues needed to be more effectively addressed in the presentation.

Once all suggested changes were incorporated, the presentation was submitted for review by a second set of focus groups, whose members mirrored the make-up of the first set of focus groups, including four focus groups of ten women each. Unlike the first set of focus groups, in which participants were read the presentation, the second set of focus groups was shown a simple PowerPoint presentation without any sound and asked to read through it.

Participants in this second set of focus groups recommended that the presentation include a voice-over superimposed onto the PowerPoint slides to minimize audience fatigue from reading the presentation in its entirety. Additional comments centered on small formatting changes, and there were virtually no new thematic suggestions for substantive changes to the content. Instead, participants in the second set of focus groups noted that some pictures did not line up evenly and that some of the slides still had too much text.

Because the changes recommended by the second set of focus groups were so minimal, after these editing and voice-over changes were incorporated into the PowerPoint presentation, no further focus group evaluations of the program were deemed necessary. The presentation was now ready for incorporation into the randomized controlled trial for evaluation of its efficacy.

Discussion

Focus group methodologies are essential when there are differences in perspectives or worldviews between researchers and the communities they are targeting [14]. This difference can stem from distinct cultural backgrounds and plays a key role in ethnic/cultural groups' disparities in cancer clinical trials. Focus groups "give a voice" to marginalized groups and thereby help to reconcile the differences among and between communities and the researchers who seek to serve them. The individuals in a focus group are viewed as the experts because they are providing their own opinions and beliefs first-hand. As can be seen in this study, focus groups generate information that helps to tailor health educational tools with appropriate cultural content and language [15]. The feedback provided from these focus groups is anticipat-

ed to have made the clinical trials educational program a more effective tool because it will more accurately reflect the understanding, perspective, and concerns of those served [15]. It theoretically should, therefore, have a better chance of producing a positive shift in knowledge, attitudes, and behaviors related to clinical trials than the program as it was originally conceived.

Because even the most carefully culturally tailored program does not guarantee a successful intervention, the next phase of this study will employ a randomized controlled trial to evaluate the impact of this educational program on participants' knowledge, attitudes, and behaviors related to clinical trials.

Conclusion

Focus group participants in this study provided the research team with many strategies and critical changes for improving the cultural alignment of the breast cancer clinical trials educational program focused on AA/HA women. The breadth and depth of their assessments of the program underscore the value of securing community input to programs destined for use with specific audiences.

Acknowledgments This project was accomplished with funding from the California Breast Cancer Research Program (CBCRP) grant 13AB-3500. Other supportive funding was provided by NIH 5P30CA023100; NIH/NCMHD 5P60MD000220; NIH 5R25CA65745; and NIH U56CA92079/U56CA92081 and 1U54CA132379/1U54CA132384. The authors acknowledge the following who played key roles in helping with this project: Mercedes Soto, Kofi Yiadom, and Vincent Bunggay of UCSD and Courtney Carter of Vista Community Clinic. Most importantly, the authors acknowledge the 80 women who generously gave of their time to participate in the focus groups.

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